Approach to Defining

and

Implementing

the

Fermilab Quality Assurance Program

Background:

Until the re-compete by DOE in 2006, Fermilab did not have a contract requirement to have a formal quality assurance (QA) program. Until that time, Fermilab Policy 10, Quality Assurance, stated, *"The attainment of a high level of quality in our operations results from the Laboratory's compliance with contractual and regulatory requirements and with each employee adopting and working to good planning habits and "work safe" practices."* Essentially, implementation of quality assurance was relegated to each individual working at Fermilab. From that perspective, nothing has changed.

With the advent of Fermilab Research Alliance (FRA) and the new contract, the DOE has placed the requirement for the laboratory to have a formalized QA program that follows the requirements of DOE O 414.1C, Quality Assurance. Just as every employee is responsible for safety, so will they be responsible for quality. The change will be in how quality is managed and controlled.

The Case for Change:

Fermilab is unique in the high energy physics (HEP) community in that it has, for years, been the operator of the most powerful particle accelerator in the world. It now finds itself on the cusp of a time when that honor is going to pass to another facility on another continent. As such, several key decisions are being made regarding Fermilab: whether to shut down or modify the Tevatron for other use, whether to fund new experiments, and the level of involvement in international collaborations such as Project 'X' and the ILC.

Fermilab is undertaking a number of improvement efforts in the following areas:

- Project planning and execution; and
- Design and engineering processes; and
- Training; and
- Quality Assurance; and
- Inter-laboratory and international project collaboration processes.

Strategy:

The strategy to building a Fermilab Quality Assurance Program has three main components:

1. The QA Plan will be built to help Fermilab achieve its major goals such as establishing the means and methods to improve operations and being prepared to host the ILC. Process improvements, an element of QA, should provide a positive influence on the laboratory from the perspective of enhanced capabilities and reputation for management and technical excellence.
2. Fermilab will use a risk-based graded approach to define the quality requirements that are applicable to laboratory activities. For example, activities that have a high risk or

high consequence if the endeavor were to encounter difficulties will have more rigorous controls established than those that have little to no consequence. The program will be compliant; however, it will only establish controls where necessary.

3. Following the model of the FESHM, there will be a single, laboratory-wide QA Plan and implementing procedures to govern the quality program. Divisions, Sections and Centers will not establish separate QA programs or procedures.

Implementation and Approach:

Discussion:

DOE O 414.1C contains 10 criteria that have to be contained in the Plan:

1. QA Program
2. Personnel Training and Qualification
3. Quality Improvement
4. Documents and Records
5. Work Processes
6. Design
7. Procurement
8. Inspection and Acceptance Testing
9. Management Assessment
10. Independent Assessment

As previously stated, a graded approach will be used to define what level of rigor must be used in each of the criterion to establish quality processes at Fermilab. Once established, the laboratory will perform reviews and audits to verify that the controls are managed appropriately and effectively.

Fermilab will establish a Quality Development Team (QDT) to establish the QA program. Each Division, Section and Center will designate a participant with line or project management experience to work with the QA Manager and an expert facilitator from EG&G, under the lead of the Office of Quality and Best Practices (OQBP). The QDT members will represent their parent organization. In this role, they will be responsible for discussing approach and processes/procedures developed within the QDT, with their management. Members of the QDT will be approved by the Assurance Council. Official reviews with their management and parent organization will be programmed throughout the process at key points on the schedule to receive acceptance before proceeding to the next steps.

The QA program will be compliant with DOE O 414.1C; however, the primary focus of the program will be to leverage the requirements for the benefit and improvement of the laboratory. The goal of implementing a proper QA program includes improving effectiveness and efficiency, process management, systematically meeting customer requirements, and budget and cost control; all of which are needed to assist Fermilab in preparation for the ILC.

It is anticipated that the QDT will discover that many of the required QA elements are in place at some level at Fermilab; just not collected into a single program with the label "QA Program". To transition to the end-state of having a centrally-controlled, lab-wide QA program, the QDT will perform the following general functions:

- Refine and publish a Project Execution Plan that contains project plans, schedules, and budget requirements in terms of program development and implementation (i.e. two distinct phases).
- Establish a standard approach and implementing documents that meets the requirements of the DOE Order and the laboratory's needs
- Establish metrics and reporting functions to demonstrate progress and compliance
- Collect and collate existing QA practices and information and correlate with the standard
- Flowchart processes
- Identify gaps that exist between the new standard and existing practices
- Establish and execute a plan to close the gaps
- Receive training in assessment and audit techniques
- Perform the first set of audits/assessments with the trainer (EG&G QA Manager) as On-The-Job training and define corrective actions to close findings and issues.
    - This will include a combination of self-assessments and cross-divisional audits to ensure reviews are objective

Exit criteria to disband the QDT will be the conclusion of the first set of programmed audits and assessments, as defined by the QA Plan and implementing documents, and acceptance of plans to reconcile findings and issues by the Divisions, Sections and Centers and the Directorate. From that point forward the Managers of the Divisions, Sections and Centers will be responsible for full implementation of the QA program. It is anticipated that the members of the QDT will become QA representatives for their Divisions, Sections or Center and will meet at a periodicity to be defined by the QDT during program development. The members will be responsible for QA activities such as maintenance of the QA program, audits and assessments, and future process improvements. OQBP will then be responsible for oversight of the program; ensuring that assessments, surveillance, and audits are planned and performed; and ensuring that issues are captured and tracked.

The Fermilab Director, the Head of the OQBP, and the Assurance Council will provide overall guidance and executive sponsorship to the process. Under the guidance of the OQBP, EG&G will provide management of QA program implementation, QDT leadership, training, coaching, and other assistance as needed.

QA Program Development Process:

The process has been started by the OQBP. A new policy generated by the OQBP has been approved by the Director and draft QA documents have been generated:

- QA Approach
- Quality Assurance Plan with Elements of –
    - DOE Order and Guides, ISO 9001, Malcolm Baldrige
    - FRA commitments & initiatives, best practices (benchmarked)
- Graded Approach Procedure
- Document Control Procedure
- Issues Tracking System User Guide
- Corrective & Preventive Action Procedure

In addition, the Quality Assurance Plan (QAP) is currently being drafted along with this document and a project execution plan (PEP). The draft QAP and PEP will be completed by the time the QDT is established. A list of reference documents and other forums used in the development of the QA program drafts is contained in Attachment 1.

In development of the QAP, the OQBP is benchmarking Argonne National Laboratory's QA program and is planning visits to SLAC, BNL, and JLAB. The draft QAP will contain requirements gleaned from the FRA contract, DOE Orders and Guides, elements of ISO 9001 and Malcolm Baldrige, FRA commitments and initiatives, and best practices gleaned from benchmarking exercises.

Once established, members of the QDT, as representatives of their respective organizations, will review the draft documents and build a list of activities that have to be considered in implementing the QA program.

A significant amount of time will be spent by the QDT in refining the graded approach procedure as it is the single document that will define the roadmap for implementation of QA at Fermilab. The assessment of risk and its commensurate applicability table needs to be tailored to the laboratory's needs so it accurately ties activities in the Divisions, Sections and Centers to the level of QA rigor required. Once the document is approved, the QDT will perform an assessment of the Divisions, Sections and Centers activities against the graded approach to define the level of QA rigor with which each Division, Section and Center will have to comply. A gap analysis will be performed between the requirements and current practices and used to form an action plan. The assessment, identified gaps, and draft action plans will be vetted through the Divisions, Sections and Centers by the members of the QDT as part of the development process.

QA Program Review and Sponsorship:

Ongoing visible, senior management support will be vital to the success of the program. To gain sponsorship, the QDT will have to generate a credible program that can be sustained.

To ensure viability, key documents and information will be briefed for comment and sponsorship to the Assurance Council, and upon approval, to the Fermilab Director at the conclusion of each of the major development stages:

- Project Execution Plan
- Quality Assurance Plan and metrics
- Graded Approach Procedure
- Gaps analysis - Draft program and existing practices
- Implementation Plan (close gaps)
- Audit Plan
- Audit results

In addition, the level of acceptance throughout the laboratory will depend strongly on how the program is viewed by management and what elements are highlighted to employees. Key to this acceptance will be emphasis on improvement for the benefit of the laboratory versus compliance to the DOE Order.

Communication:

Communications will be provided to Fermilab using a variety of tools including staff meetings and Fermilab Today articles. Specific communication events will occur at the same points as the briefs to the Assurance Council/Fermilab Director to keep employees abreast of developments and progress. In addition, the EG&G QA Manager and QDT members will offer to speak at small meetings with Fermilab staff to help with understanding and to get feedback.

Document Control:

All of the QA program documents will be under configuration management by the document control procedure. The documents will be numbered and managed under version control to ensure that changes and their associated basis are captured. Once approved, they will be placed in a centralized, document control website. All laboratory personnel will have access to the electronic version and controlled copies of printed documents will be released at specific locations to be determined by the QDT.

Process Improvement:

It is anticipated that areas that require improvement will be identified during the development of the QA program. As part of the program development, a procedure will be developed that provides specific process improvement methodology. It will borrow and codify best practices such as process flowcharts, decision trees, affinity diagrams, run charts, etc. from sources such as Malcolm Baldridge, Six-Sigma, Lean Thinking, Theory of Constraints, ISO 9000, Total Quality Management, Just-In-Time, and Benchmarking.

Process improvement will follow standard practices, such as DMAIC; or Define, Measure, Analyze, Improve, and Control as the situation warrants. Personnel that will be involved with the process improvement will be trained in the selected method(s) prior to commencement and have the EG&G expert to rely upon for guidance and facilitation.

These process improvement evolutions will be conducted outside of the QA program QDT or wait until the QA program implementation is complete if the same members are required.

Startup:

The kickoff for this project will take approximately one week, followed by QDT meetings every 2 weeks. The QDT may meet less frequently once the program is developed and assessments are being performed. Adjustments to the meeting schedule will be the responsibility of the QDT.

The kickoff week will include:

- Brainstorming the approach
- Identifying lessons learned from previous projects of a similar nature
- Discussing how risk is going to be identified, calculated, managed, and mitigated
    - Known issues, risks, and associated mitigating actions will be identified and tracked from the beginning of the project
    - Identification of potential issues that can't initially be qualified or quantified will be noted for monitoring during the project execution
- Identifying project constraints in terms of budget, schedule, manpower, and known issues
- Identifying, discussing, and assigning key project members/functions roles and responsibilities:
    - Project Manager
    - QDT Members
    - Budget
    - Procurement
    - Integration and Risk Manager
    - Project Controls
- Interaction between QDT and site
- Documentation and Configuration Control
- Communication

Themes:

The following are themes that will be used in discussions about the benefits of establishing a QA program at Fermilab:

- Demonstrated world class science, management, and operations
- Using management tools designed to improve the probability of being selected to host the ILC at Fermilab
    - Embedding ISO 9001 processes into the fabric of the QA program in order to be in a state of readiness for formal certification and increased credibility with ILC site selection committee

- Improving laboratory performance will result in less re-work and therefore more time and money available for science. Ultimately this will lead to improved productivity and reputation.
- Defining a process and providing procedures that encourage Fermilab employees to engage in discovering opportunities for improvement.
- Establishing new processes such as a formal Lessons Learned program will allow future projects to learn from our mistakes and avoid recurrence - these can also be passed to other DOE National Labs as appropriate.
- QA done right is value added to Fermilab.

Change Control

Changes to the QA Plan, implementation plans and schedule, not significantly affecting major milestones, will be reviewed and approved by the Head of the OQBP prior to be accepted. OQBP will communicate these changes and project status to site DOE by holding regularly scheduled meetings.

- Monthly for the first quarter of calendar 2008
- Quarterly thereafter, unless otherwise agreed to

Changes having a significant impact on schedule and key deliverables will be reviewed and approved by OQBP and site DOE prior to being accepted. Key milestone deliverables include:

- December 31, 2007 QA Plan Draft Ax Rev 000 to DOE review
- January 31, 2008 Draft updated QA Ay Plan Rev 000 to DOE review
- February 25, 2008 Graded Approach Rev 000 signed
- March 17, 2008 Contractor Assurance document to DOE review
- March 22, 2008 Rev 000 QA Plan signed and to DOE
- March 24, 2008 Management, QA Plan Orientation
- March 24, 2008 Site, QA Plan Orientation
- April 14, 2008 Rev 000 Contractor Assurance Document signed
- April 24, 2008 Audit/assessment Training
- May 9, 2008 Draft Quality Assurance Audit Plan Rev 000 to DOE review
- May 9, 2008 Draft Contractor Assurance Audit Plan Rev 000 to DOE review
- May 30, 2008 Quality Assurance Audit Plan Rev 000 signed
- May 30, 2008 Contractor Assurance Audit Plan Rev 000 signed
- July 14, 2008 QA Project Plan to DOE review
- August 11, 2008 QA Project Plan Rev 000 signed
- September 30, 2008 Gap Analysis QA Plan Draft Rev 001 for review
- October 31, 2008 Draft Rev 001 QA Plan to DOE review
- November 24, 2008 QA Implementation Plan to DOE review
- December 31, 2008 QA Plan Rev 001 signed
- January 30, 2009 QA Project Plan Rev 000 updated

- February 6, 2009 QA Project Plan Rev 001 signed
- February 6, 2009 QA Implementation Team established

Attachment 1 – Reference Documents and Forums used in Development of QA Program Draft Documents

Requirements Review:

- DOE O 414.1C, Quality Assurance
- DOE O 226.1, Implementation of Department of Energy Oversight Policy
- FRA Contract No. DE-AC02-07CH11359
    - Section I87 Management Controls including section b on QA Program
    - Section I88 Performance Improvement and Collaboration
    - Appendix B, Section J.2 Performance Evaluation Measurement Plan
    - Appendix B, Section J.9 DOE Directives / Fermilab Work Smart Standards
- FRA and EG&G Commitments and Initiatives
- ANSI/ASQ/ISO Q9001-2000, Quality Management Systems – Requirements
- ANSI/ASQ Z1.13-1999, Quality Guidelines for Research
- Previous or existing quality documents including but not limited to;
    - Fermilab QA Program circa 1993-1994 in compliance with DOE O 5700.6C
    - Technical Division's current QA Plan and specific project QA Plans

Current Fermilab Meetings and Other Media:

- Key meetings including:
    - Fermilab Assurance Council
    - Scheduling Meeting
    - LHC Triplets Remediation Meeting
- Fermilab documents and literature:
    - Emails, Memos, and Reports
    - Fermilab Today, Symmetry, etc.
- Briefings (formal and informal) with key personnel:
    - Fermilab Head of OQBP, COO, Division, Section and Center Heads
    - Fermilab Divisions personnel
    - Fermilab Sections including, ES&H, Tech. Pubs & Records Management, BSS, (MIS) Finance,
    - EG&G Program Manager and EG&G Director of Performance Assurance